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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/301,766 | 04/29/1999 | EIJIRO WATANABE | 0020-4559P | 6045 |

2292 7590 01/30/2008
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

| EXAMINER | |
|---|---|
| KRUSE, DAVID H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 01/30/2008 | ELECTRONIC |

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/301,766
Filing Date: April 29, 1999
Appellant(s): WATANABE ET AL.

Mark J. Nuell
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 1 November 2007 appealing from the Office action mailed 23 August 2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal No: 2007-4459
Appellant: EIJIRO WATANABE et al.
Application No: 08/992,914

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

As a clarifying note, the Examiner had indicated that pending claims 6 and 7 are allowable.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

1. Duggleby, Gene 190:245-249 (1997), cited by the Examiner in the Office Actions of February 6, 2002 and November 20, 2002.

2. Bowie et al., Science 247:1306-1310 (1990), cited by the Examiner in the Office Action November 20, 2002.

3. Lazar et al., Molecular, Cellular Biology 8:1247-1252 (1988), cited by the Examiner in the Office Action of November 20, 2002.

4. Broun et al., Science 282:1315-1317 (1998), cited by the Examiner in the Office Action of November 20, 2002.

5. Richmond et al., Plant Physiol. 124:495-498 (2000), cited by the Examiner in the Office Action of August 11, 2003.

6. Peterbauer et al., Planta 215:839-846 (2002), cited by the Examiner in the Office Action of August 11, 2003 and December 2, 2005.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**(A)** Claims 1, 4, 5, 8-10, 16-23 and 28-29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is

maintained for the reason of record as set forth in the Final Rejection mailed 23 August 2006. Appellant's arguments filed 1 November 2007 have been fully considered but they are not persuasive.

The instant claims are directed to an isolated nucleic acid encoding a protein that binds a D-galactosyl group through the α(1-6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose, having a specified nucleotide sequence, encoding a specific amino acid sequence, or obtained by PCR using specified primers and that hybridizes to a complementary nucleotide sequence under specified condition. The claims are also directed to a vector and transformant comprising said nucleic acid, and a method for producing raffinose using said transformant.

The instant application describes a *Brassica juncea* polynucleotide (SEQ ID No: 6) encoding a raffinose synthase enzyme (SEQ ID NO: 5).

The instant application does not describe any function for the protein encoded by SEQ ID NO: 4 or 8. SEQ ID NO: 7 and 8 only describe a partial amino acid and nucleic acid sequence, respectively and hence do not describe an isolated nucleic acid encoding a protein having raffinose synthase activity (claim 1 (e), (f) and (h); claims 8-10). The instant application does not adequately describe the genus isolated nucleic acids from beet, mustard or rapeseed encoding a protein having raffinose synthase activity that are obtained by PCR using the recited primers and that would hybridize to a complement of such nucleotide sequences under the recited conditions.

Hence, it is unclear that Appellant was in possession of the invention as broadly claimed.

**(B)** Claims 1, 4, 5, 8-10, 16-23 and 28-29 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 5, plants transformed therewith and methods of using such isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids encoding raffinose synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is maintained for the reason of record as set forth in the Final Rejection mailed 23 August 2006. Appellant's arguments filed 1 November 2007 have been fully considered but they are not persuasive.

The instant claims are directed to an isolated nucleic acid encoding a protein that binds a D-galactosyl group through the $\alpha$(1-6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose (raffinose synthase), having a specified nucleotide sequence, encoding a specific amino acid sequence, or obtained by PCR using specified primers and that hybridizes to a complementary nucleotide sequence under specified condition. The claims are also directed to a vector and transformant comprising said nucleic acid, and a method for producing raffinose using said transformant.

The instant application teaches a *Brassica juncea* polynucleotide encoding a raffinose synthase enzyme (SEQ ID NO: 6 which encodes SEQ ID NO: 5).

The instant application does not teach any function for the protein encoded by SEQ ID NO: 4 or 8. SEQ ID NO: 7 and 8 only teach a partial amino acid and nucleic acid sequence, respectively and hence do not teach an isolated nucleic acid encoding a protein having raffinose synthase activity (claim 1 (e), (f) and (h); claims 8-10). The instant application does not adequately enable one of skill in the art how to make and use the genus isolated nucleic acids from beet, mustard or rapeseed encoding a protein having raffinose synthase activity that are obtained by PCR using the recited primers and that would hybridize to a complement of such nucleotide sequences under the recited conditions.

The instant application has only taught how to make and use an isolated nucleic acid encoding a raffinose synthase having the amino acid sequence of SEQ ID NO: 5. The teachings of the art as to the relative skill of those in the art to distinguish the function of a protein having raffinose synthase simply based on amino acid sequence similarity can be found in previous Office actions. The art teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proven by experiments designed to evaluate that function (Duggleby 1997, Gene 190:245-249, see page 248, left column, last paragraph, cited in a previous Office action). Hence, given the breadth of the claims, the amount of guidance provided by the instant application on how to make and use other raffinose synthase encoding nucleic acids, the state of the art at the time of the instant invention and the relative skill of those in the art at the time of the invention, it would have required undue trial and error

experimentation by one of skill in the art at the time of the invention to make and use the invention as broadly claimed.

**(10) Response to Argument**

**(A)** *VIIA. Rejections Under 35 U.S.C. § 112, first paragraph – written description*

VIIA.1. Claim 1: Appellant argues that there are no "bright line" tests for whether or not a specification provides adequate written description of a claimed invention. Appellant argues that the Examiner must carefully review the claims, and carefully review the specification to determine whether, in view of what is known in the art at the time the application was filed, the specification provides evidence that the inventor was in "possession" of the invention as claimed (page 12 of the Brief). The Examiner is in agreement with Appellant's argument.

Appellant argues that as to the Examiner's first assertion, SEQ ID NO: 7 (encoded by nucleotides 1 to 1719 of SEQ ID NO: 8) is indeed only a partial sequence of a raffinose synthase; about 25% of the full-length sequence is missing from the amino-terminal end. Appellant argues that the instant claim 1 does not recite that the claimed polynucleotide "consists of" the recited sequence, rather, the claim recites that the polynucleotide "comprises" the recited polynucleotide, and hence also includes any amino acids necessary to complete an amino acid sequence of a raffinose synthase protein. Appellant argues that the two such complete amino acid sequences are disclosed in the present application as SEQ ID NOS: 3 and 5. Appellant argues that methods for determining the complete nucleotide sequence of a cDNA encoding raffinose synthase from rapeseed are explained in the specification, as used to obtain

complete sequences are obtained for examples from beet and mustard. Appellant argues that one of ordinary skill in the art might simply obtain the missing portion of the enzyme from the complete cDNAs for these two proteins that are described (SEQ ID NOS: 2 and 4). Appellant argues that the Board is reminded that claim 1 specifically includes as a feature that the encoded protein exhibit a recited enzymatic activity and so inoperable embodiments are excluded from the claim. Appellant argues that it is clear that the specification evidences that the inventors had in their possession the invention claimed in claim 1, parts (e) and (f). Appellant argues that the Examiner has merely stated a summary conclusion, parroting guidelines to the effect that the specification must set forth an explicit "structure-function relationship" used by the USPTO to implement a policy restricting cloned gene inventions to specifically disclosed species, rather than carefully considering the facts presented by the instant application and claims as required by Federal Circuit case law. Appellant argues that notwithstanding the failure of the Examiner to carefully consider the facts of the present application, he is simply wrong that the specification does not explain parts of the RFS sequence that should be preserved for activity. Appellant argues that the specification explains that certain portions of the amino acid sequence of a RFS should be constrained to high homology to SEQ ID NO: 3 or to SEQ ID NO: 5, see, pp. 20-21, indicating portions of high homology (accounting for both sequences) from amino acids 103 to 213, 255 to 275, 289 to 326 and 609 to 696 (page 13 of the Brief). These arguments are not found to be persuasive. The description of a partial coding sequence, and hence a partial encoded amino acid sequence, does not adequately describe a protein having the

claimed function. Appellant has argued that the Examiner must carefully review the claims, and carefully review the specification to determine whether, in view of what is known in the art at the time the application was filed, the specification provides evidence that the inventor was in "possession" of the invention as claimed (see above). In response to Appellant's argument, in the instant case there had been very few raffinose synthase encoding polynucleotides isolated and characterized in the art at the time of the instant invention. Given the breadth of the claimed invention, it remains the Examiner's opinion that one skilled in the instant art would not have recognized that Appellant had possession of the invention as broadly claimed because one skilled in the art could not have been assured that an isolated polynucleotide actually encoded a raffinose synthase without empirical evidence of function. The Examiner cannot find Appellant's asserted support for constrained amino acid sequences of a RFS at pages 20-21 of the specification which describes degenerate PCR primers. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent

property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

Appellant argues that the present specification describes in detail a method for cloning raffinose synthase (RFS) genes from plants of broadly diverse genera (*Glycine, Beta, Brassica*). Appellant argues that the specification describes using sequence information of a cDNA encoding part of a RFS from *Glycine max* (SEQ ID NO: 2) to prepare a set of PCR primers that will hybridize to a degenerate set of sequences that are used to amplify mRNA obtained from other plants and so isolate fragments of RFS cDNA. Appellant argues that these initial amplification products are sequenced, then that further data are used to prepare a new set of primers specific for RFS for the particular plant being studied. Appellant argues that the second set of primers is used to make new amplification products that are cloned and from which the complete sequence of the cDNA is obtained (see, the Examples 1-6 of the specification). Appellant argues that this approach was used three times in working examples of the present specification to successfully obtain RFS cDNAs from three different plants. Appellant argues that the complete coding portions of the cDNA for *Beta vulgaris* and *Brassica juncea* (SEQ ID NOS: 4 and 6, respectively) and part of the coding portion of a cDNA from *Brassica napus* (SEQ ID NO: 8) are presented. Appellants have presented evidence in the form of a Declaration of Dr. Watanabe that demonstrates unequivocally that a protein having the amino acid sequence of SEQ ID NO: 5 has biological activity of

a RFS, and this is not disputed by the Examiner. Appellant argues that plainly the approach described in the specification can be used successfully to isolate a cDNA encoding RFS from diverse genera of plants (page 14 of the Brief). These arguments are not found to be persuasive. The Examiner affirms Appellant's argument that the *Brassica juncea* sequence of SEQ ID NO: 5 (encoding SEQ ID NO: 6) describes a raffinose synthase species. Appellant's arguments concerning other sequences or the breadth of the claimed invention are not found to be persuasive. A description of a process by which a nucleic acid encoding a raffinose synthase enzyme may be isolated does not inherently describe the isolated nucleic acid. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, the Examiner has addressed the breadth of the limitations "beet" and "mustard or rapeseed" in the Office action mailed on 2 December 2005, pages 5-7.

Beet:

*Beta altissima,* Steud.

*Beta brasiliensis,* hort. ex Voss

*Beta chilensis,* hort.

*Beta cicla*, L. L.

*Beta vulgaris* var. *altissima,* Döll

*Beta vulgaris* subsp. *cicla*, L. W. D. J. Koch

*Beta vulgaris* var. *cicla,* L.

*Beta vulgaris* cv. *conditiva,* Alef.

*Beta vulgaris* var. *crassa,* Alef.

*Beta vulgaris* subsp. *flavescens,* Lam.

*Beta vulgaris* var. *flavescens*, Lam. DC.

*Beta vulgaris* f. *rhodopleura*, Alef. Helm

*Beta vulgaris* cv. *saccharifera,* Alef.

Mustard or rapeseed:

| | |
|---|---|
| *Alliaria petiolata*, M. Bieb. Cavara & Grande | garlic mustard |
| *Brassica carinata*, A. Braun | Abyssinian mustard, Ethiopian mustard, mustard collard |
| *Brassica juncea*, L. Czern. | India mustard, Indian mustard, Oriental mustard |
| *Brassica juncea* var. *crispifolia,* L. H. Bailey | curled mustard, cut-leaf mustard, dissected-leaf mustard, southern curled mustard |
| *Brassica juncea* var. *foliosa,* L. H. Bailey | leaf mustard |
| *Brassica juncea* var. *japonica*, Thunb. | cut-leaf mustard, dissected-leaf |

| | |
|---|---|
| L. H. Bailey | mustard |
| *Brassica juncea* var. *juncea* | brown mustard, Indian mustard |
| *Brassica juncea* var. *longidens,* L. H. Bailey | hakka mustard |
| *Brassica juncea* var. *multiceps,* N. Tsen & S. N. Lee | chicken mustard, multishoot mustard, nine-head mustard |
| *Brassica juncea* var. *napiformis,* Pailleux & Bois Kitam. | large-root mustard, root mustard, tuberous-root mustard, turnip-root mustard |
| *Brassica juncea* var. *rugosa*, Roxb. N. Tsen & S. N. Lee | cabbage-leaf mustard, head mustard, Swatow mustard |
| *Brassica juncea* var. *strumata,* N. Tsen & S. N. Lee | chopped mustard, horned mustard, large-petiole mustard |
| *Brassica juncea* var. *tumida,* N. Tsen & S. N. Lee | big-stem mustard, swollen-stem mustard |
| *Brassica nigra*, L. W. D. J. Koch | black mustard |
| *Brassica rapa* subsp. *Campestris*, L. A. R. Clapham | field mustard |
| *Brassica rapa* subsp. *Chinensis*, L. Hanelt | celery mustard, Chinese mustard, mustard cabbage, white celery mustard |
| *Brassica rapa* subsp. *Narinosa*, L. H. Bailey Hanelt | broad-beak mustard |
| *Brassica rapa* var. *perviridis,* L. H. Bailey | spinach mustard |
| *Brassica rapa* var. *purpuraria*, L. H. Bailey Kitam. | purple-stem mustard |
| *Brassica* spp. | wild mustard |
| *Brassica tournefortii,* Gouan | African mustard |
| *Bunias orientalis,* L. | hill mustard |

| | |
|---|---|
| *Chorispora tenella*, Pall. DC. | blue mustard, musk mustard, purple mustard |
| *Cleome gynandra,* L. | bastard-mustard |
| *Conringia orientalis*, L. Dumort. | hare's-ear mustard |
| *Descurainia incana*, Bernh. ex Fisch. & C. A. Mey. Dorn | gray tansy mustard |
| *Descurainia pinnata*, Walter Britton | tansy mustard, western tansy mustard |
| *Descurainia torulosa,* Rollins | Wyoming tansy mustard |
| *Diplotaxis tenuifolia*, L. DC. | sand mustard |
| *Erucastrum gallicum*, Willd. O. E. Schulz | dog mustard |
| *Erysimum cheiranthoides,* L. | wormseed mustard |
| *Erysimum repandum,* L. | treacle mustard |
| *Eutrema penlandii*, Rollins | Penland alpine fen-mustard |
| *Glaucocarpum suffrutescens*, Rollins Rollins | shrubby reed-mustard |
| *Neslia paniculata*, L. Desv. | ball mustard |
| *Rapistrum rugosum*, L. All. | common giant mustard |
| *Schoenocrambe argillacea*, S. L. Welsh & N. D. Atwood Rollins | clay reed-mustard |
| *Schoenocrambe barnebyi*, S. L. Welsh & N. D. Atwood Rollins | Barneby's reed-mustard |
| *Sinapis alba,* L. | white mustard |
| *Sinapis alba* subsp. *alba* | white mustard |
| *Sinapis arvensis* subsp. *arvensis* | wild mustard |
| *Sisymbrium altissimum,* L. | tumble mustard |
| *Sisymbrium officinale*, L. Scop. | hedge mustard, tumble mustard |

| | |
|---|---|
| *Thelypodium stenopetalum*, S. Watson | slender-petal mustard |
| *Thlaspi arvense,* L. | Mithridate mustard |
| *Turritis glabra,* L. | tower mustard |
| *Warea carteri,* Small | Carter's mustard. |

Appellant argues that they have presented substantial evidence that one of ordinary skill in the art can distinguish RFS from STS members of the glycoside hydrolase family. Appellant argues that this evidence is in the form of the data in Tables 1 and 2 and Figure 1 presented with Appellants' Amendment filed February 11, 2004 and in Table 3 and Exhibit 1 presented with Appellants' Amendment filed November 15, 2004. Appellant argues that these data, and the Exhibit supporting the robustness of the analysis, show that RFS enzymes are distinguishable from STS enzymes by determination of the degree of sequence identity to SEQ ID NO: 1, 3, 5 or 7 according to the present specification. Appellant argues that the data show that RFS enzymes among themselves are at least 50% identical at the amino acid level, and that STS enzymes are similarly homologous to each other (actually a bit more so, about 65%). Appellant argues that the degree of identity between RFS and STS enzymes is at most about 45%. Appellant argues that sequence identity analysis permits the artisan of ordinary skill to illustrate the distinction between RFSs and STSs by a "dendrogram", as shown in Figure 1 attached to the Amendment filed February 11, 2004 (page 15 of the Brief). These arguments are not found to be persuasive. The evidence presented does not support the written description in the instant application at the time of the invention.

Appellant argues that they have argued that the specification of the co-pending application 08/992,914, which discloses additional examples of RFS cDNAs cloned essentially in the manner described in the present specification, provides another example in which biological activity of a RFS cDNAs is demonstrated, and that this demonstration further evidences the effectiveness of the methods described in the present specification in obtaining cDNAs encoding RFS proteins (page 15, 3rd paragraph of the Brief). This argument is not found to be persuasive. The Examiner notes that the instant application shares no common priority with, or claim of priority to co-pending application 08/992,914, and hence cannot rely upon said co-pending application under 35 U.S.C. § 112, first paragraph for support under Written Description.

Appellant argues that in order to meet the requirements for adequate written description, the specification must provide evidence that the inventors "possessed" the invention as claimed at the time the application was filed. Vas-Cath v. Murhurkar 19 USPQ2d 1111 (Fed. Cir. 1991). Appellant argues that the evidentiary standard that must be met by Appellants is only that of the preponderance of the evidence, see, *In re Oetiker,* 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Appellant argues that the Examiner seems to be improperly requiring that Appellants meet a higher evidentiary burden, i.e. "clear and convincing" evidence or even "beyond reasonable doubt." Appellant argues that the evidence of record in the present application firmly establishes that it is "more likely than not" that all of the sequences disclosed in the present application are those of RFS enzymes. Appellant argues that this has been unequivocally established by biochemical assay for one disclosed sequence, and sequence similarity as analyzed by

one of ordinary skill in the art establishes that it is more likely than not true for the others. Appellant argues that the same approach for cloning RFS-encoding cDNAs used in the present application has been further applied by the Appellants, as described in a copending application, and yet a further demonstration that the approach obtains cDNA encoding an RFS enzyme, as determined by assay of another expressed cDNA, has been made. Appellant argues that the present specification, by showing reduction to practice of four species of the claimed invention obtained from three diverse genera of plants, adequately evidences that the inventors "had possession" of the claimed invention at the time the present application was filed (page 16 of the Brief). These conclusionary arguments are not found to be persuasive and have been substantially addressed above.

VIIA.2. Claims 4 and 5: Appellant argues that claims 4 and 5 recite specific sequences at either the nucleotide or amino acid level and that the skilled artisan can readily determine the exact structure or family of structures encompassed by the claims and so there is no question that the inventors "possessed" the inventions described in these two claims (page 17 of the Brief). This argument is not found to be persuasive because the invention of claims 4 and 5 require a specific function, which the instant application does not sufficiently describe.

VIIA.3. Claims 8 and 9: Appellant argues, concerning claims 8 and 9, that the regions of high homology within raffinose synthases described in the specification are indicated by the shaded portions of the sequence. Appellant argues that the missing 4% of that region (or for that matter the entirety of the missing amino-terminal portion) may

be supplied by the corresponding amino-terminal end sequences of SEQ ID NO: 3 or 5 as desired by the practitioner of the invention. Appellant argues that they have also explained above that the evidence of record in the present application is sufficient, at least to the standard of the preponderance of the evidence, to establish that the amino acid sequence of SEQ ID NO: 7 is that of a RFS enzyme (page 18 of the Brief). This argument is not found to be persuasive for the reasons given above.

VIIA.4. Claim 10: Appellant argues that claim 10 recites a group of specific structures that are expressly stated in the Sequence Listing as originally filed. Appellant argues that there can be no doubt that the specification describes these sequences exactly and so no doubt that claim 10 meets the requirement for written description of the claimed invention (page 19 of the Brief). This argument is not found to be persuasive because the invention of claim 10 requires a specific function, which the instant application does not sufficiently describe.

VIIA.5. Claims 16-23, 28 and 29: Appellant argues that the Examiner has so far presented no reason for rejection of claims 16-23, 28 and 29 independent from the rejection of claim 1. Appellant argues that the Board is respectfully requested to consider that, should the decision of the Examiner with respect to any part (a) through (h) of claim 1 be reversed, the dependent claims 16-23, 28 and 29 should be indicated as allowable if rewritten to recite the allowable part of claim 1 (pages 19-20 of the Brief). As these claims, as Appellant points out, depend from claim 1, they stand or fall with claim 1 for the reasons of record. As dependent claims, all of the limitations of the claim(s) upon which they depend are read into said dependent claims.

**(B)** *VIIB. Rejections under 35 U.S.C. § 112, first paragraph – enablement*

VIIB.1. Claim 1: Appellant argues that the Examiner has never established a proper *prima facie* case for lack of enablement of the claimed invention. Appellant argues that proper analysis of the question of enablement requires that the factors of 1) the breadth of the claims, 2) the nature of the invention, 3) the level of ordinary skill in the art, 4) the amount of experimentation needed, 5) the state of the art at the time the invention was made, 6) the amount and quality of guidance provided by the specification, 7) the presence or absence of working examples and 8) the predictability in the art. Appellant argues that of these factors, the Examiner repeatedly has only addressed the predictability in the art. Appellant argues that the Examiner's position is that, because there is evidence in the record for RFS activity only for a protein of amino acid sequence of SEQ ID NO: 5, and the degree of sequence identity among the amino acid sequences identified in the working examples is as low as 50%, Appellants cannot reliably assign the biochemical activity of a raffinose synthase to the amino acid sequences of SEQ ID NOs: 3 and 7 (page 21 of the Brief). These arguments are not found to be persuasive. In the Office action mailed on 2 December 2005, the Examiner clearly stated that "given the general skill of those of skill in the art, the nature of raffinose synthase enzymes relatedness of other enzymes and the limited guidance by Applicants it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use raffinose synthase encoding nucleic acids as broadly claimed". Hence, the Examiner had addressed several Wands

factors when determining the scope of enablement of the instant claims.

Appellant argues that the Examiner's analysis of the question of undue experimentation looks only at the factor of whether working examples of the claimed invention are described in the specification and an assertion that it is unpredictable whether any particular nucleic acid produced according to the teachings of the invention would in fact exhibit raffinose synthase activity. Appellant argues that this analysis is legally insufficient to establish *prima facie* lack of enablement, as the Examiner fails to consider the breadth of the claims, the nature of the invention, the level of ordinary skill in the art, the quantity of the experimentation needed, the guidance provided by the specification (other than the presence or absence of working examples) and the state of the art at the time the invention was made. Appellant argues that the kind of predictability, a prior knowledge of functionality of the enzyme obtained using the methods of the invention, is not the kind of predictability envisioned by the Court in Wands (pages 21-22 of the Brief). These arguments are not found to be persuasive for the reason given above.

Appellant argues that inoperative embodiments are excluded from the claims by the requirement that the encoded protein have RFS activity. Appellant argues that the art of molecular biology, in particular the art of expression of recombinant proteins, is one in which the artisan of ordinary skill expects to perform a few weeks or months of experimentation in generating variants of a protein, then isolating clones encoding those variants and then (perhaps) re-cloning the isolated variants into vectors for expressing a protein, and then screening expressed proteins for activity (pages 22-23 of the Brief).

Appellant argues that the amount of experimentation needed to practice the present invention is not unduly large or burdensome. Appellant argues that the practitioner must isolate a template genomic DNA or RNA from an organism, perform a polymerase chain reaction using primers described in the specification to generate an amplified fragment, clone that fragment into an expression vector, express the encoded protein and then screen the protein for activity as a raffinose synthase. Appellant argues that all of these steps are either well-known in the art or described in detail in the specification (e.g. pp. 31-33 (bacterial expression of the cloned cDNA and assay for RFS activity and Examples 1-6 beginning at p. 38) and furthermore are expected to be performed by the artisan of ordinary skill (page 23 of the Brief). These arguments are not found to be persuasive. The Examiner notes that the hybridization conditions recited at claim 1 (g) and (h) "0.9M NaCl and 0.09M citric acid" is recognized in the instant art and low to moderate hybridization conditions, and would isolate a large number of nucleic acids. Said claim does not recite any specific PCR conditions by which the "product-by-process" is produced. As to Appellant's argument that the cloned cDNA and assay for RFS activity are expected to be performed by the artisan of ordinary skill, this argument is not found to be persuasive because Appellant is arguing limitations not in the claim.

Appellant argues that at the time the invention was made, the state of the art of molecular biology was such that the various laboratory operations that must be performed to carry out the experimentation required to practice the instant invention, i.e. cloning of DNA molecules and expressing them in a host cell, were routine. Appellant argues that polymerase chain reaction amplification of nucleic acids was routine.

Appellant argues that the raffinose content of a number of organisms, especially including plants and some algae, was known. Appellant argues that the biochemistry of raffinose synthesis in plants had been established, and the role of raffinose synthases as rate-limiting of raffinose production was known. (See, e.g. pp. 1-2 of the specification). Appellant argues that a biochemical assay for raffinose synthase activity was described (See Lehle et al., Eur. J. Biochem. 38:103 (1973) (attached)). Appellant argues that the guidance provided by the specification including the presence or absence of working examples Appellant argues that the specification provides ample guidance to the skilled artisan for practicing the invention broadly. In particular, the specification discloses in detail how to clone DNAs encoding putative raffinose synthase enzymes. Appellant argues that the specification provides details such as organisms likely to be useful for isolating template genomic DNA or RNA from plants commensurate in scope with claim 1 and corresponding PCR primers (Chenopdiceae (for beet), p. 11, line 14; Cruciferae (for mustard and rapeseed), p. 13, line 18 and associated PCR primers in Lists 2 and 3). Appellant argues that the specification describes methods for cloning DNA encoding a putative raffinose synthase enzyme from an RNA fraction, including an extensive list of primers that can be utilized for PCR amplification from templates obtained from different organisms (see, e.g. Lists 6 and 7 at p. 43; Lists 8 and 9 at page 46; List 10 at p. 47). Appellant argues that the specification describes methods for expressing the cloned DNA in plant cells and in bacteria (see, e.g. pages 29 to 37). Appellant argues that the specification describes a biochemical assay for raffinose synthase, referring to the Lehle article noted above and

summarizing the procedure beginning at the bottom of page 31. Appellant argues that the specification also provides a number of working examples of isolation of partial or complete raffinose synthase genes from a number of different plants (see, Examples 1-7) and of creation of an expression vector for use in plants (Example 8) transformation of a plant (mustard) with a cloned DNA encoding a raffinose synthase (Example 9) (pages 23-24 of the Brief). These arguments are not found to be persuasive, because as stated above Appellant is arguing limitations (bacterial expression and enzyme assays) not recited in the claim(s).

Appellant argues that the skilled artisan can follow detailed teachings in the specification of how to clone, express and evaluate DNAs that are likely to encode functional raffinose synthase enzymes. Appellant argues that it is true that it is a bit unpredictable whether any individual clone made in an experiment will include a DNA encoding a functional enzyme, but it is not unpredictable whether the skilled artisan would succeed in identifying at least one functional DNA in an experiment as a whole, and that to the contrary, it is very likely that the skilled artisan would find a cloned DNA encoding a functional enzyme by following the teachings of the specification. Appellant argues that the experimental approach described in the specification resulted in identification of four cDNAs described in this application and additional cDNAs as described in the co-pending '914 application (page 25 of the Brief). These arguments are not found to be persuasive. One of the bases of the instant rejection is the Examiner's issue of whether the instant specification actually teaches more than one actual raffinose synthase encoding polynucleotide, wherein the specification assumes

that the other taught polynucleotides encode a raffinose synthase enzyme based of amino acid similarity and plant source with only about 50-89% sequence similarity. The instant specification does not teach any structural feature that would be recognized by one of skill in the art at the time of the invention, identifying a raffinose synthase and distinguish a raffinose synthase for other encoded proteins.

Appellant argues that they have provided evidence in the form of the Watanabe Declaration attached to their Amendment of February 11, 2004, to support an assertion that the procedures described in the specification result in cloning of cDNAs encoding RFS enzymes. Appellant argues that they have also provided evidence that one of ordinary skill in the art can readily distinguish a RFS from a STS or another class of closely related proteins, Seed Imbibation Proteins (SIPs). Appellant argues that the data in Figure 1 attached to Appellants' Amendment of February 11, 2004, and submitted as part of the Nagasawa Declaration (copied from the '914 application file and submitted with Appellants' Amendment of June 2, 2006) demonstrates unequivocally that the RFS subfamily of glycoside hydrolases (see Appellants' discussion of Peterbauer et al., below) is easily distinguished from the STS or SIP subfamilies of glycoside hydrolases on the basis that RFSs are more similar to each other, and STSs are more similar to each other, than RFSs are similar to STSs. Appellant argues that this relationship among their amino acid sequences can be used to construct a "molecular phylogenetic tree" upon a branch of which any particular amino acid sequence thought to represent a RFS or STS (or SIP) can be placed. Appellant argues that the Nagasawa Declaration further explains that this analysis is robust in its conclusions (though perhaps the

specific degrees of sequence similarity may vary) to three different approaches to sequence similarity analysis (page 26 of the Brief). These arguments are not found to be persuasive. The Watanabe Declaration teaches that the nucleic acid of SEQ ID NO: 5, encoding SEQ ID NO: 6, was enabled and actually encoded a raffinose synthase enzyme. This evidence did not, in the Examiner's opinion, enable the full scope of the claimed invention. See the Office action mailed 1 March 2005, page 7.

Appellant argues that the Examiner has attempted to support his position regarding unpredictability in the art with evidence from the scientific literature. The Examiner has cited Richmond et al. Plant Physiology (2000) and Duggleby, Gene (1997) for a general assertion that, "The art teaches that one of skill in the art cannot assume the function of the polypeptide encoded by an isolated nucleic acid solely based on sequence similarity to a known polypeptide sequence. Appellant argues that these concepts are well-known to the molecular biologist of ordinary skill in the art and they do suggest that it is somewhat unpredictable whether mutating a protein will result in maintaining, lessening or improving its biological activity, however, this is not determinative of whether undue experimentation is required to practice the instant invention. Appellant argues that all that such unpredictability establishes is that, without actual assay data, one cannot say beyond reasonable doubt that a mutated protein will retain its original activity. Appellant argues that this is not the proper standard of evidence to consider during patent prosecution. Appellant argues that their burden is to only establish that it is more likely than not that the proteins of amino acid sequences 3 and 7 represent a protein having RFS activity, or that a cDNA obtained as described in

parts (g) and (h) of claim 1 encodes such a protein (pages 26-27 of the Brief). These arguments are not found to be persuasive. The Examiner cited said references to show that in the instant art, one of skill in the art can not always assume function just based on protein sequence similarity. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.".

Appellant argues that Richmond might be interpreted as more supportive of Appellants' position that sequence similarity is a useful tool for grouping proteins by activity. Appellant argues that the Board might take note of Figure 1 of the paper, showing assignment of members of the family to subfamilies CesA, CesB, CesD, etc. based upon a molecular phylogeny. Appellant argues that the Board may usefully compare Figure 1 of Richmond with Figure 1 attached to the Nagasawa Declaration, which shows a similar molecular phylogeny among RFSs, STSs and a SIP, with the result of clear separation of the three groups of enzymes (page 27, 3rd paragraph of the Brief). These arguments are not found to be persuasive. Richmond clearly states on

page 497 that "Recent results concerning the relationship between enzyme structure and function, such as experiments showing that as few as four amino acid changes can alter the catalytic outcome of an enzymatic reaction from desaturation to hydroxylation...emphasize the need for caution in using sequence similarity to infer function based on sequence". Hence, it is the Examiner's opinion that Richmond supports the instant rejection for the reasons of record.

Appellant argues that for purposes of alleging utility in a patent application, the standard of proof is merely the preponderance of the evidence. Appellant argues that Duggleby has no problem asserting function from sequence similarity. Appellant argues that the Board might consider the text of the Note Added In Proof: "Recent examination of GenBank expressed sequence tags has identified three sequences ... that may represent higher plant ALS small subunits. Appellant argues that the last of these gives a very good match to the *P. purpurea* sequence; over residues 83-154 there are 46 identical, and 10 similar, amino acids." Appellant argues that the Board might further note that the author's conclusion is based upon a degree of identity of only 71% at the amino acid level of a partial amino acid sequence (page 28, 1st paragraph of the Brief). These arguments are not found to be persuasive. The Examiner notes that Duggleby also teaches a highly conserved amino acid sequence at figure 2 on page 247 that supported the conclusion, but still stated that empirical evidence was still necessary (page 248. left column, 4th paragraph, lines 14-17).

Appellant argues that the Duggleby paper describes study of the small subunit of the acetolactate synthase (ALS) from a bacterium, yeast and an alga. Appellant argues

that the paper provides an alignment of the genes from these three organisms (Figure 2). Appellant argues that the authors note that there is only "limited similarity" among the three sequences, but nonetheless were able to detect a number of known bacterial ALS genes and also discovered the eukaryotic versions of the gene using a BLAST search of GENBANK and the bacterial sequence (*B. flavum*) as a query (See, p. 247, under Results and Discussion). Appellant argues that Duggleby in fact also supports Appellants' assertion that comparison of sequence data is a common technique in the art for predicting biochemical function of a protein. ("These results clearly indicate that *S. cerevisiae* and *P. purpurea* contain a gene that could encode an ALS small subunit." (at the top of the right column on p. 247.)) (page 28, 2nd paragraph of the Brief). These arguments are not found to be persuasive for the reason given above.

Appellant argues that Peterbauer (2002) describes isolation of a raffinose synthase gene from *P. sativum* (pea). Appellant argues that the Examiner asserts that Peterbauer teaches that RFSs, STSs and SIPs demonstrate high overall sequence homology, and that this has not been disputed by Appellants. Appellant argues that Peterbauer discusses this result in terms of assignment of all three of these enzyme types to the glycoside hydrolase enzyme family (p. 841, right column, above Figure 1). Appellant argues that RFSs are more alike, and STSs are more alike, than RFSs resemble STSs and therefore these members of the glycoside hydrolase family are distinguishable subfamilies (page 28, 3rd paragraph of the Brief).

Appellant argues that the Examiner has read Peterbauer (2002) rather selectively. Appellant argues that at the top of the right column on p. 841, Peterbauer

easily distinguishes a STS transcript from a RFS transcript on the basis of sequence identity. Appellant argues that Peterbauer uses an approach to cloning the pea RFS gene that is similar to that described in the present specification, that is, PCR primers designed from the amino acid sequence of the RFS were used to amplify template DNA from the pea plant. Appellant argues that then the resulting cDNA was expressed in a cell and the protein so produced was assayed for RFS activity. Appellant argues that these teachings may usefully be compared with the working examples 1-6 of the present specification and the Watanabe Declaration (page 29 of the Brief). These arguments are not found to be persuasive because Peterbauer is post filing art. Peterbauer states at page 843, right column, 3rd paragraph that "Direct evidence of hydrolytic activity of raffinose synthase towards galactinol could not be provided, because we were unable to purify recombinant protein". Peterbauer also teaches that using the distinguishing primers they isolated a stachyose synthase mRNA (page 841, right column, 1st paragraph, lines 12-14.

Appellant argues that Peterbauer (2002) does not particularly support the Examiner's position. Appellant argues that the authors note that, "to distinguish between raffinose synthase and stachyose synthase, the primers were chosen to encompass a block of about 80 amino acids, which is exclusively present in stachyoses synthases." (Top of page 841, right column), this establishes that there are in fact amino acid sequence elements that serve to distinguish a RFS from a STS. Appellant argues that the Examiner has read the paper very selectively, urging the data showing sequence similarity, but ignoring for example, the text at the top of the right column of p. 841, "To

isolate a cDNA encoding for raffinose synthase by reverse transcription-PCR, degenerate primers were designed based upon amino acid motifs conserved among *Cucumis sativa* raffinose synthase, stachyose synthase and related sequences." Appellant argues that thus Peterbauer et al were satisfied that they could reliably distinguish among such sequences either by biochemical or sequence analysis methods. Appellant argues that none of the papers proffered by the Examiner in rebuttal of Appellants' arguments is effective to undermine either their argument that the specification is enabling of practice of the invention, or the evidence of the Nagasawa Declaration that one of ordinary skill in the art can readily determine by amino acid sequence analysis whether a given amino acid sequence represents a RFS, a STS or a SIP (page 29, 3rd and 4th paragraphs of the Brief). These arguments are not found to be persuasive for the reasons given above.

VIIB.2. – claim 4: Appellant argues that the breadth of claim 4 is substantially narrower than the breadth of claim 1. Appellant argues that the amino acid sequence of SEQ ID NO: 3 is of the complete length of the protein and the degree of sequence identity to SEQ ID NO: 5, proven to represent an enzyme having RFS activity in the Watanabe Declaration, is 63%, substantially higher than the degree of identity between a RFS and STS (see, Table 2 attached to Appellants' Amendment of February 11, 2004). Appellant argues that the degree of unpredictability as to whether SEQ ID NO: 3 encodes a RFS enzyme or not may be considered to be lower than that for claim 1 as a whole, and so enablement of claim 4 should be weighed separately from enablement of claim 1 (page 30, 2nd paragraph of the Brief). This argument is not found to be

persuasive, as stated above the evidence required in the instant art to enable the claims is substantially higher "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved".

VIIB.3. – claim 5: As directed to claim 5, Appellant argues that the degree of unpredictability as to whether SEQ ID NO: 4 encodes a RFS enzyme or not may be considered to be lower than that for claim 1 as a whole. Appellant argues that the only experimentation necessary to determine conclusively whether the sequence SEQ ID NO: 4 in fact does encode a RFS enzyme is to clone this sequence into an expression vector, transform a bacterial or plant host cell with the vector and test the transformed bacteria or plant tissue for expression of RFS activity in the manner described in the specification (See, e.g. pp. 31-37 of the specification). Appellant argues that such experimentation must be considered well-guided by the specification and expected by the artisan of ordinary skill, and so not "undue". Appellant argues that the specification, at page 26, line 13 to page 28, line 21, describes use of nucleic acids of the invention in genotyping analysis or for detection of mutation in raffinose synthase genes or for marking cloned plant varieties. These utilities are independent of whether or not the cloned DNA encodes a protein having raffinose synthase activity, for example, a nucleic acid encoding only a part of a raffinose synthase gene is adequate for use in such methods. Appellant argues that at least for genotyping and plant variety identification even nucleic acids unrelated to raffinose synthase genes are useful (pages 30-31 of the Brief). This argument is not found to be persuasive for the reason given above (VII.B.2).

VII.B.5 – Claim 8: As directed to claim 8, Appellant argues that the breadth of this

claim is substantially narrower than the breadth of claim 1, therefore, the degree of unpredictability as to whether SEQ ID NO: 8 encodes a RFS enzyme or not may be considered to be lower than that for claim 1 as a whole, and so enablement of claim 9 should be weighed separately from enablement of claim 1 (pages 31-32 of the Brief). This argument is not found to be persuasive for the reason given above (VII.B.2).

VII.B.6 – Claim 9: As directed to claim 9, Appellant argues that the only experimentation necessary to determine conclusively whether the sequence SEQ ID NO: 8 in fact does encode a RFS enzyme is to clone this sequence into an expression vector, transform a bacterial or plant host cell with the vector and test the transformed bacteria or plant tissue for expression of RFS activity in the manner described in the specification, (See, e.g. pp. 31-37 of the specification). Appellant argues that such experimentation must be considered well-guided by the specification and expected by the artisan of ordinary skill and so not "undue". Appellant argues that the specification, at page 26, line 13 to page 28, line 21, describes use of nucleic acids of the invention in genotyping analysis or for detection of mutation in raffinose synthase genes or for marking cloned plant varieties. Appellant argues that these utilities are independent of whether or not the cloned DNA encodes a protein having raffinose synthase activity, for example, a nucleic acid encoding only a part of a raffinose synthase gene is adequate for use in such methods. Appellant argues that at least for genotyping and plant variety identification even nucleic acids unrelated to raffinose synthase genes are useful (page 32, 3rd paragraph of the Brief). These arguments are not found to be persuasive for the reasons given above (VII.B.1).

VII.B.7 – Claim 10: As directed to claim 10, Appellant argues that the breadth of this claim is substantially narrower than the breadth of claim 1, therefore, the degree of unpredictability as to whether SEQ ID NOs: 4 and 8 encode a RFS enzyme or not may be considered to be lower than that for claim 1 as a whole, and so enablement of claim 10 should be weighed separately from enablement of claim 1. Appellant argues that the only experimentation necessary to determine conclusively whether the sequences SEQ ID NO: 4 and 8 in fact do encode a RFS enzyme is to clone these sequences into an expression vector, transform a bacterial or plant host cell with the vector and test the transformed bacteria or plant tissue for expression of RFS activity in the manner described in the specification (See, e.g. pp. 31-37 of the specification). Appellant argues that such experimentation must be considered well-guided by the specification and expected by one of ordinary skill in the art and so not "undue". Appellant argues that the specification, at page 26, line 13 to page 28, line 21, describes use of nucleic acids of the invention in genotyping analysis or for detection of mutation in raffinose synthase genes or for marking cloned plant varieties. Appellant argues that these utilities are independent of whether or not the cloned DNA encodes a protein having raffinose synthase activity, for example, a nucleic acid encoding only a part of a raffinose synthase gene is adequate for use in such methods. Appellant argues that at least for genotyping and plant variety identification even nucleic acids unrelated to raffinose synthase genes are useful (pages 33-34 of the Brief). These arguments are not found to be persuasive for the reasons given above (VII.B.1)

VII.C.8 – Claims 16-23, 28 and 29: Appellant argues that claims 16-23, 28 and 29

are dependent ultimately from claim 1 and stand rejected for the same reasons as claim 1 is rejected. Appellant argues that the Examiner has so far presented no reasons for rejection of these claims independent from the rejection of claim 1 (page 34 of the Brief). As these claims, as Appellant points out, depend from claim 1, they stand or fall with claim 1 for the reasons of record. As dependent claims, all of the limitations of the claim(s) upon which they depend are read into said dependent claims.

**(C)** *VII.C. – Summary and Conclusion*

Appellant argues that in the first instance, the specification asserts that the defined sequences in SEQ ID NOs: 1-8 (of which SEQ ID NOs: 3-8 are recited in claims) define nucleic acids according to the invention, either at the nucleic acid or at the amino acid level. Appellant argues that specific description of a structure constitutes substantial evidence that they "possess" the invention so described and have placed such an invention in the hands of the public. Vas-Cath v. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). Appellant argues that the specification describes a number of PCR primers, derived from the data of SEQ ID NOs: 2, 4, 6 and 8 or otherwise, that are useful when applied to template nucleic acids from plant types associated with the primer sequences as described in the specification, to obtain further cloned cDNAs encoding raffinose synthase enzymes. Appellant argues that the specification also describes how to test any nucleic acids obtained by such a technique for activity of a raffinose synthase. Appellant argues that the invention is at the very least well-described in "product-by-process" terms. Fiefs v. Revel, 25 USPQ2d at 1605. Appellant argues that one may also consider that the PCR primers represent minimal nucleotide

sequences that must be present to define a nucleic acid as one encoding a raffinose synthase. Appellant argues that the specification, at pages 20-21, describes particular regions of amino acid sequence that should have high homology to SEQ ID NO: 3, which is an amino acid sequence shown by Declaration evidence to represent a protein having RFS activity., therefore, to this degree at least, a "structure-function" relationship is described in the specification (page 35, 2nd and 3rd paragraphs of the Brief).

Appellant argues that the specification meets the legal standard for adequate written description of the claimed invention, i.e. it evidences that the inventors were in possession of the invention as claimed. Appellant argues that proper consideration of the question of enablement requires establishing that undue experimentation is required to practice the full scope of the invention. Appellant argues that this question is addressed by considering a number of factors. In re Wands, 8 USPQ2d at 1400. Appellant argues that the Examiner's explanation of the rejection addresses only the question of whether one of ordinary skill in the art, having a particular nucleic acid in hand, can predict, based upon its sequence, whether or not that nucleic acid encodes a raffinose synthase enzyme, or whether instead it encodes a stachyose synthase. Appellant argues that such analysis ignores the other factors to be considered. Appellant argues that on the other hand, Appellants explain that the specification is enabling of the claimed invention, addressing the remaining considerations required under Wands. Appellant argues that they also present evidence to support an allegation that the skilled artisan, using the teachings of the specification in a manner accepted in the art at the time the invention was made (e.g. molecular phylogeny based upon

degree of amino acid sequence similarity) can easily distinguish a raffinose synthase enzyme from a stachyose synthase enzyme. Appellant argues that they also point out that the specification provides express guidance of how to determine biochemically if a protein expressed from a cloned nucleic acid exhibits activity of a raffinose synthase. Appellant argues that as to claims 5, 9 and 10, directed to particular nucleic acids encoding raffinose synthase enzymes, the specification describes utilities for the cloned nucleic acids that are independent of whether they actually encode a functional enzyme. Appellant argues that for these three claims, the Examiner's entire rationale for making the rejection fails (pages 36-37 of the Brief).

The Examiner has substantially addressed all of these arguments in the above section VIIB. The rejections are maintained for the reasons of record.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/David H Kruse/
David H Kruse
Primary Examiner
AU 1638

Conferees:

/Anne Marie Grunberg/
Anne Marie Grunberg
Supervisory Patent Examiner
Supervisory Patent Examiner
AU 1638 and 1661

/Joseph Woitach/
Joseph T. Woitach
Supervisory Patent Examiner
AU 1633